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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,204	12/21/2000	Helena Seppanen	09910-007001	5981

7590 12/12/2003

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	13

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,204	SEPPANEN ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Newgrounds of Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 7-14, 15, 16, 17, 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins (US 5,705,628) further in view of Smith et al. (US 4,272,510).

Hawkins teaches a method of DNA purification and isolation using magnetic particles. The method comprises of incubating single stranded DNA and magnetic particles in a microtiter plate; Add 100 ul of binding buffer (20% PEG 8000 and 2.5 M NaCl) which corresponds to the surface tension releasing agent in the present invention and mix; magnetically separate the particles and remove the DNA to a new microtiter plate. The magnetic particles used were the carboxyl coated magnetic microparticles which were 1 um in diameter. (see col. 9, lines 20-30; example 4).

However, Hawkins fails to teach using a magnetic probe to separate the magnetic particles from the mixture and transferring the magnetic particles to the next medium.

Smith et al. teaches means for applying magnetic force to move antigen-antibody coated solid phase units from one place to another, i.e. from a predispensed reaction mixture to reaction mixture, into and out of large volumes of rinsing fluids and finally to test tubes or vials which are to be inserted into a gamma counter. The solid phase unit comprises a core of ferrous metal (core of magnetic material).

It would have been obvious to one of ordinary skills in the art to use the magnetic separation device of Smith et al. to separate bound magnetic particles in the method of Hawkins because Hawkins suggests magnetic separation step and transferring the magnetic particles to a second medium/vessel. By using the magnetic separation means of Smith, the magnetic separation step of Hawkins' method would be carried out at a faster pace thus would save much time and effort and the particles can be transferred to as many vessels as possible. Also, by using such combination, a large number of solid phases units (particles) can be separated simultaneously under extreme uniform conditions, so as to yield highly reproducible results in solid phase assays with large numbers of specimen. Regarding the concentration the magnetic particles, it would have been obvious to one of ordinary skill in the art to adjust such concentration to execute optimum binding between the magnetic particle and the target analyte.

Regarding claim 17, one of ordinary skills in the art would find it obvious to add a STRAs in all the mediums through routine experimentation.

Claims 1-6, 9, 13, 14, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czerlinski (US 4, 454,234) further in view of Smith et al. (US 4,272,510).

Czerlinski teaches a method for separating magnetic particles. The rabbit anti-BSA antibodies, a given quantity (50 to 100 ul of BSA per 10 ml tube) of BSA-coated magnetic particles are added to a series of tubes. To each tube, a surface tension releasing agent such as a protein of rabbit antiserum diluted in PBS containing 2% (v/v) of normal sheep serum and 0.05% Tween 20 is added. The magnetic particles are collected with a magnet, washed with 4 ml of PBS containing 0.05% Tween 20. They are collected and resuspended a total of three times. (see example 3).

However, Czerlinski fails to teach using a magnetic probe to collect the magnetic particles and transfer them to a second medium.

Smith has been discussed above.

It would have been obvious to one of ordinary skills in the art to use the magnetic separation device of Smith for the magnetic separation step in Czerlinski's method because such as device would accelerate the collection of the magnetic particles and thus would accelerate the speed of the separation step so that results would be obtained at a faster rate since the method of Czerlinski requires that the magnetic particles must be collected and resuspended a total of three times. Regarding the

concentration of the tenside, one of ordinary skills in the art would be able to arrive at a suitable range through routine experimentation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
December 8, 2003

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641